

REMARKS

A. Claim Amendments.

Claims 5, 6, 17, 23, 27, 28 and 29-31 were previously withdrawn as being drawn to non-elected claims. Claim 33 is canceled as depending from a previously withdrawn claim. Claims 24-26 were previously canceled. In anticipation of allowance, the previously withdrawn claims are now cancelled, without prejudice to their later presentation in a divisional application. The claims pending after amendment are therefore Claims 1-4, 7-16, 18-22, 24-26, and 32.

Claims 1 and 12 are amended to recite that the fatty acid ester that is the single active ingredient for killing ectoparasites utilized is one that effectively kills them within an hour of contact. Support for the claim language is found in the Specification at, for example, paragraphs 0036 and 0039. No new matter is added by this amendment, which places the claims in condition for allowance. Entry thereof is therefore requested.

B. Response to Rejection under Section 102(a) & (e), based on Pearlman.

Claims 1-4, 7, 12-15, 18, 32 and 33 stand rejected under Section 102(a) and (e) based on Pearlman, US Patent No. 6,303,581, on the basis that Pearlman discloses that "6 seconds to 4 hours suffices to remove the composition." (Office Action at page 4, sixth paragraph, citing to Pearlman at Col. 13, lines 12-20 and Col. 15, "top"). Applicant respectfully disagrees.

As discussed in the prior amendment, the compositions of the present invention kill ectoparasites, whereas those of Pearlman principally act to immobilize lice to facilitate their removal from the scalp. To that end, Pearlman requires that the compositions applied be "driable"; i.e., that they be left on the lice for a sufficient period of time to become dry (*see, e.g.,* column 7, lines 61-62).

If one were to remove the Pearlman compositions in “6 seconds to 4 hours” as contended in the Office Action, doing so would not cause the treated lice to die, as required by the present claims. Indeed, according to Pearlman, killing lice is unnecessary to his invention (Col. 8, lines 1-2). Instead, Pearlman teaches that, using the preferred embodiment of CETAPHIL cleanser, treated lice can be immobilized to an extent that they could be pulled from the scalp *but would still be alive and mobile again if so removed within 6 seconds to 4 hours of application:*

CETAPHIL® Cleanser has the ability rapidly to trigger the "immersion reflex" in head lice. Both in vivo and in vitro, lice coated in CETAPHIL® Cleanser became immobilized within 6 seconds. On the patients' scalp, the lice became totally immobilized, floating on the scalp in the Cleanser. They were easily removed by forceps without any effort to escape or to grasp the hair shaft to stay in place. Under the microscope, they were immobile did not respond to being touched, and lost their normally visible gut motility. They remained immobilized as long as they were in the Cleanser. *This phenomenon was observed for periods ranging from 6 seconds to 4 hours. At any point prior to drying the cleanser, the louse could be removed from the Cleanser and usually awakened and resumed crawling. When immersed overnight in CETAPHIL® Cleanser (12 hours) the lice died.*

*When CETAPHIL® Cleanser was dried onto lice (6 lice tested), the lice remained immobile. When the dried agent was removed by redissolving it in water after 4 hours of contact, the lice recovered and regained mobility. When left on the lice for more than 8 hours before redissolving, the lice died.*

*Pearlman, '581, at Col. 14, line 64 to Col. 15, line 18, emphasis added.*

As noted by Pearlman above, even when his compositions are dried onto treated lice (e.g., by a blow drier), lice die only when the treatment is left “on the lice for more than 8 hours before redissolving.” With air drying, the process takes even longer—at least 12 hours. Therefore, Pearlman does not teach a method for killing ectoparasites by

applying a fatty acid ester thereto that kills them within an hour of contact. Nor does he provide the art with any guidance whatsoever as to how one might select a fatty acid ester that has such robust activity.

To the contrary, Pearlman contains only two references to fatty acid esters. In the first, at Col. 12, line 2, fatty acid esters of fatty alcohols are mentioned as being among many potential non-ionic surfactants that could find use in the invention, with propylene glycol being identified as the preferred choice. Nothing in this reference points one to particular fatty acid esters, much less those useful in killing ectoparasites within an hour of contact. To the contrary, Pearlman points the art only to surfactants that *do not* kill ectoparasites within the recited time frame, but merely temporarily immobilize them. In this aspect, therefore, Pearlman teaches away from the invention, as claimed.

In the second reference to fatty acid esters, Pearlman again teaches away from the invention by requiring the ester to be admixed *with an alcohol*; see, Col. 12, lines 35-46. In this aspect, Pearlman further teaches away from the invention as claimed.

From a functional perspective, Pearlman only requires that the components of his invention be drier, whereby killing only occurs with completion of drying (see, e.g., Col. 14, line 62 through Col. 15, line 18). The only composition whose activity and drying is exemplified in the reference is one that does not contain any fatty acid ester at all (CETAPHIL® Cleanser; see, Col. 14, lines 46-53 and line 62 through Col. 13, line 3), and which only dries without application of heat if left in place for 8 to 12 hours (Col. 15, lines 1- 18).

In contrast, the compositions of the invention contain fatty acid ester actives that kill within an hour (see, e.g., Example 3—lice morbidity was up to 100% after an application of only 10 minutes, after which the composition was removed and morbidity determined at 24 hours), and do so *before* becoming dry (see, e.g., the study of record performed in 2000 at Harvard, Spielman, <http://www.hsph.harvard.edu/headlice.html>, 2000: more than 1 hour is required for lice to suffocate in an oil-based agent; and, Murphy, et al., US Pat.

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4,414,200: cyclodimethicone requires as long as 72 hours to fully dry at 25-30°C, even when admixed with isopropyl myristate [see, Col. 3, lines 40-44 and Col. 4, lines 32-65]).

Therefore, nothing in Pearlman provides the art with any guidance at all toward selection of fatty acid esters with the robustly lethal activity of those whose use is presently claimed. To the contrary, Pearlman teaches only the selection of fatty acid esters which kill ectoparasites, if at all, only after drying after long exposure (8+ hours, versus the one hour recited in the present claims), or which are used in combination with other agents, including alcohols (whose use is excluded by the present claims).

Further, Pearlman does not contain any suggestion of compositions that kill ectoparasites by stripping them of their waxy cuticle, per Claim 12. To the contrary, Pearlman teaches that any death among lice treated according to his invention occurs, if at all, through suffocation (see, e.g., Col. 3, lines 17-20).

Therefore, contrary to the requisites of the present claims, Pearlman therefore teaches away from the explicit limitations of the claims, and so does not anticipate the invention.

Reconsideration and withdrawal of the rejection under Section 102(a) and/or (e) is therefore requested.

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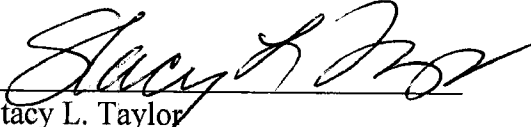
## CONCLUSION

All of the pending claims (1-4, 7-16, 18-22, 24-26, and 32) are believed to be in condition for allowance. Reconsideration of the claims rejections and objections is therefore requested as outlined above.

The Commissioner is hereby authorized to charge \$635.00 as payment for the Petition for Two-Month Extension of Time fee (\$230.00) and Request for Continued Examination fee (\$405.00) to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

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